

Serial No. 10/032,238

Docket No. 0075.00

AMENDMENTSIn the Claims:

Please cancel claims 23, 33 and 41-43 without prejudice. In addition, please amend claims 1, 24 and 26-29 as indicated below. Currently amended claims are presented with markings to indicate the changes made, wherein ~~strike through~~ is used to designate deleted subject matter and underlining is used to designate added subject matter.

1. (Currently amended) A powder composition comprising spray-dried particles ~~comprised~~ consistently essentially of soluble interleukin-4 receptor (~~IL-4R~~) (sIL-4R) as an active agent and one or more excipients selected from the group consisting of carbohydrates, lipids, divalent metal cation, buffers, amino acids, oligopeptides, peptides, and proteins, wherein the powder composition comprises particles having a mass median aerodynamic diameter (MMAD) of less than about 10 microns.

2. (Previously presented) The composition of claim 1, having a monomer content and an aggregate level that is essentially unchanged relative to that of its pre-spray dried solution or suspension.

3. (Previously presented) The composition of claim 1, characterized by a decrease in monomer content as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.

4. (Previously presented) The composition of claim 3, characterized by an extent of formation of aggregates as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.

5. (Original) The composition of claim 1, being moisture stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content, as compared to the level of aggregate and monomer content of its pre-spray dried solution or suspension, under humid conditions.

Serial No. 10/032,238
Docket No. 0075.00

6. (Previously presented) The composition of claim 5, characterized by a decrease in monomer content of not more than 10% when determined after storage of said composition for 14 days at 33% relative humidity.
7. (Previously presented) The composition of claim 5, characterized by a decrease in monomer content of not more than 7% when determined after storage of said composition for 14 days at 33% relative humidity.
8. (Previously presented) The composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 33% relative humidity.
9. (Previously presented) The composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 75% relative humidity.
10. (Previously presented) The composition of claim 5, characterized by formation of less than 10% insoluble aggregates in water after storage for 14 days at 33% relative humidity.
11. (Previously presented) The composition of claim 1, characterized by formation of less than 7% insoluble aggregates in water upon storage for 14 days at 33% relative humidity.
12. (Previously presented) The composition of claim 1, characterized by formation of less than 5% insoluble aggregates upon storage for 14 days at 33% relative humidity.
13. (Previously presented) The composition of claim 1, characterized by formation of less than 5% insoluble aggregates upon storage for 14 days at 75% relative humidity.
14. (Previously presented) The composition of claim 1, being temperature stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content,

Serial No. 10/032,238

Docket No. 0075.00

as compared to the level of aggregate and monomer content of its pre-spray dried solutions or suspension, under extreme temperatures.

15. (Previously presented) The composition of claim 14, characterized by a decrease in monomer content of not more than 10% after storage for 14 days at 2 to 8°C or 40 to 50°C.

16. (Previously presented) The composition of claim 14, characterized by a decrease in monomer content of not more than 7% after storage for 14 days at 2 to 8°C. or 40 to 50°C.

17. (Previously presented) The composition of claim 14, characterized by a decrease in monomer content of not more than 5% after storage for 14 days at 2 to 8°C. or 40 to 50°C.

18. (Previously presented) The composition of claim 14, characterized by formation of less than 10% insoluble aggregates after storage for 14 days at 2 to 8°C. or 40 to 50°C.

19. (Previously presented) The composition of claim 14, characterized by formation of less than 7% insoluble aggregates after storage for 14 days at 2 to 8°C. or 40 to 50°C.

20. (Previously presented) The composition of claim 14, characterized by formation of less than 5% insoluble aggregates after storage for 14 days at 2 to 8°C or 40 to 50°C.

21. (Previous presented) The composition of claim 1 in aerosolized form.

22. (Previously presented) The composition of claim 1 substantially free from excipients.

23. (Canceled).

24. (Currently amended). The composition of claim ~~23~~ 1, wherein ~~the excipient~~ one of the one or more excipients is selected from the group consisting of carbohydrates a carbohydrate, ~~amino acids, oligopeptides, peptides, and proteins.~~

Serial No. 10/032,238

Docket No. 0075.00

25. (Previously amended) The composition of claim 24, wherein said carbohydrate is a sugar or sugar alcohol.

26. (Currently amended) The composition of ~~claim 24~~ claim 1, wherein said amino acid is a hydrophobic amino acid.

27. (Currently amended) The composition of ~~claim 23~~ claim 1, wherein said excipient is selected from the group consisting of citrate salts, leucine, raffinose, zinc salts, and combinations thereof.

28. (Currently amended) The composition of ~~claim 23~~ claim 1, wherein said excipient is a buffer.

29. (Currently amended) The composition of ~~claim 23~~ claim 1, wherein said excipient is a divalent metal cation.

30. (Previously presented) The composition of claim 1, characterized by an emitted dose of at least 30%.

31. (Previously presented) The composition of claim 30, characterized by an emitted dose of at least 45%.

32. (Previously presented) The composition of claim 31, characterized by an emitted dose of at least 60%.

33. (Canceled).

34. (Previously presented) The composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 5 microns.

Serial No. 10/032,238

Docket No. 0075.00

35. (Previously presented) The composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 3.5 microns.

36. (Previously presented) The composition of claim 1, comprising particles having a mass median diameter (MMAD) of between about 0.1 to 3 microns.

37. (Previously presented) The composition of claim 1, wherein the residual moisture content is less than about 10% by weight.

38. (Previously presented) The composition of claim 37, having a residual moisture content of less than about 5% by weight.

39. (Previously presented) The composition of claim 1, wherein said composition has a bulk density ranging from about 0.1-10 g/cc.

40. (Original) The powder composition of claim 1, in a unit dosage form.

41. (Canceled).

42. (Canceled).

43. (Canceled).

(This space intentionally left blank.)